

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of:  
Epstein et al.

Application No.: 09/117,838

Examiner: Peselev, Eli

Filed: August 12, 1998

Group Art Unit: 1623

For: MEDICINAL PREPARATION

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

**AMENDED BRIEF ON APPEAL UNDER 37 CFR 41.37**

Further to the Notice of Appeal filed on March 17, 2009 for the subject application, and in response to the Notification of Non-Compliant Appeal Brief that was mailed on April 13, 2009, this brief in support of the Appeal is now submitted. Submission of the Amended Brief in support of the Appeal is due by May 13, 2009. Accordingly, this paper is being timely filed.

No fee is believed due in connection with this submission. If, however, any fee is due, such fee should be charged to Deposit Account No. 50-4711.

1. Real Party in Interest

The real parties in interest are Dr. Oleg Epstein, the assignee of the application.

2. Related Appeals and Interferences

There are no appeals or interferences that are related to this appeal, or which will effect or have a bearing on this appeal.

3. Status of the Claims

Claims 17, 19-21, 23, 25-27, 29-34 and 38-48 are pending, claims 1-16, 18, 22, 24, 28 and 35-37 were previously cancelled.

Claims 17, 19-21, 23, 25-27, 29-34 and 38-48 were finally rejected in an Office Action mailed on October 8, 2008. In an Amendment under 37 C.F.R. §1.116 to be filed subsequently to this Appeal Brief, Applicants will cancel claims 46-48 to facilitate the resolution of the issues in the present appeal. Accordingly, claims 17, 19-21, 23, 25-27, 29-34 and 38-45 are the subject of this appeal. Claims 46-48 will not be addressed herein.

4. Status of Amendments

All amended claims and new claims on appeal had been entered in the file wrapper prior to the final rejection.

5. Summary of Claimed Subject Matter

The patent application on appeal is directed to an entirely new class of medicines, denoted by the inventors as “bipathic” medications (Specification, 3: 20-26). Bipathy is a phenomena based on the demonstrated ability of the homeopathic dose of a substance to effect properties of the same substance in a standard dose (Specification, 3: 20-26).

The fundamental nature of the bipathy phenomena was demonstrated in the post-filing showing made in the Declaration of Dr. Oleg Epstein filed on February 8, 2008 (“the *Epstein Declaration*”). For example, the evidence in the *Epstein Declaration* established that when a homeopathic dose of adenosine triphosphoric acid (ATP) was added, *in vitro*, to a solution containing a normal dose of an ATP salt, the rate of ATP hydrolysis was reduced by 12.5% (with

verifiable statistical significance) as compared with the rate of hydrolysis found for reference solution of ATP (*Epstein Declaration*, par. 8). Likewise, the evidence in the *Epstein Declaration* demonstrated that the homeopathic dose of an antibody effects binding between an antibody to morphine and its morphine antigen. The addition of the homeopathic dose of the antibody to morphine reduced the binding affinity between morphine and an antibody to morphine by 30% (*Epstein Declaration*, par. 10).

The bipathy phenomenon manifests itself in biological systems and has direct applicability to medical treatment. The inventors have discovered that when a standard therapeutic dose of an active pharmaceutical substance is treated with (admixed with or incorporated with) a homeopathic dose of the same active substance, the resulting combination medicine has beneficial properties absent in the untreated active substance, including increased therapeutic efficiency and a reduction of adverse side effects (Specification, 3: 26-31). For example, a homeopathic dose of prednisolone enhances the anti-inflammatory effect of the standard dose of prednisolone (Specification: Example 3; *Epstein Declaration*, pars. 6 and 7), a homeopathic dose of aspirin enhances analgesic properties of aspirin (Specification, Example 2), a homeopathic dose of phenazepam enhanced anxiolytic and anticonvulsive effect connected with administration of phenazepam in a standard dose (*Epstein Declaration*, par. 21). A number of other examples are set forth in the Specification and/or were introduced during the prosecution, and are discussed herein below.

Independent claim 17 is directed to a method of making a bipathic medication by providing an active medicinal substance in a therapeutic dose, providing a homeopathic dilution of said active substance, and admixing or incorporating the components to produce the bipathic medication.

Independent claim 23 is directed to a bipathic medication that comprises a pharmaceutically active combination of a therapeutic dose of an active medicinal substance and a homeopathic dilution of the active substance, admixed with one another, “wherein said pharmaceutically-active combination possesses enhanced therapeutic properties in comparison with said active medicinal substance alone, said enhanced therapeutic properties being enhanced therapeutic effectiveness or reduced side effects.”

The dependent claims are directed to various embodiments of the invention.

A copy of the appealed claims is appended hereto, beginning on page 15.

6. Grounds of Rejection to be Reviewed on Appeal

A. Whether claims 17, 19-21, 23, 25-27, 29-34 and 38-45 are anticipated under 35 U.S.C. § 102(b) by the prior art of record?

B. Whether claims 17, 19-21, 23, 25-27, 29-34 and 38-45 are obvious under 35 U.S.C. § 103 over the prior art of record?

7. Grouping of Claims

Claim Group 1: Claims 23, 25-27, 29-34, and 38-45 should be considered together.

Claim Group 2: Claims 17 and 19-21 should be considered together.

8. Argument

A. Rejection of Claims 23, 25-27, 29-34 and 38-45 as Anticipated under 35 U.S.C. § 102(b)

Independent claim 17 and independent claim 23 do not stand or fall together. Thus, independent claim 17 includes distinct steps of providing a homeopathic dose and admixing the homeopathic dose with a standard dose. Any prior art process over which invalidity is alleged must disclose these claimed process steps. Independent claim 17 and independent claim 23 are addressed separately.

Claims 23, 25-27, 29-34 and 38-45 stand rejected as anticipated by the prior art of record, namely, with respect to claims 17, 19-21, 23, 25-27, 33, 43, and 45 by U.S. Patent No. 4,292,324 to Jonsson (“*Jonsson*”), with respect to claims 29 and 38 by U.S. Patent No. 3,901,967 to Cohen (“*Cohen*”), with respect to claims 30 and 39 by U.S. Patent No. 4,987,127 to Sirany (“*Sirany*”), respect to claims 31, 40, and 41 by U.S. Patent No. 3,134,718 to Nobile (“*Nobile*”), with respect to claims 32 and 42 by U.S. Patent No. 4,839,341 to Massey (“*Massey*”), with respect to claims 43 and 44 by U.S. Patent No. 3,032,584 to John (“*John*”). All of the cited references raise similar legal issues and will be discussed together.

Independent claim 23 recites:

23. A bipathic medication comprising a pharmaceutically active combination of

- i) a therapeutic dose of an active medicinal substance; and
- ii) a homeopathic dilution of said active medicinal substance;

said active medicinal substance and said homeopathic dilution being admixed or incorporated with one another;

wherein said pharmaceutically-active combination possesses enhanced therapeutic properties in comparison with said active medicinal substance alone, said enhanced therapeutic properties being enhanced therapeutic effectiveness or reduced side effects.

Therefore, the invention of the rejected claim 23 recites a pharmaceutical combination in which a therapeutic dose of a medicinal substance is admixed with (treated by) a homeopathic dilution of the same medicinal substance so that the combination possesses claimed properties different from the untreated substance in a therapeutic dose. As explained herein above, the underlying invention is based on the discovery that a homeopathic dose of a substance modifies the properties of the substance in a standard dose.

The prior art references cited by the Examiner disclose well-known pharmaceutically active compounds present at therapeutic doses. The prior art of record does not disclose a homeopathic dose or a homeopathic dilution of any substance or a combination of a homeopathic dose with a standard dose. The prior art of record plainly does not disclose the effects of the homeopathic dose on the standard dose of a substance. In this regard, the Examiner has stated:

Applicant contends that a therapeutic medicine and a homeopathic dilution of said medicine are not the same. This argument has not been found persuasive since applicant has not pointed out how the structural formula of a therapeutic medicine differs from the structural formula of a homeopathic dilution of said medicine. The claimed composition encompass nothing more than combining the same medicine in different concentration resulting in medicine disclosed in the prior art of record.

See Final Office Action mailed October 8, 2008, at pages 4-5. The Examiner continued:

Applicant further contends that the prior art of record does not disclose a therapeutically active compound that possess enhanced therapeutic properties in comparison with said active medicine alone. This argument has not been found persuasive since applicant has not presented data comparing the claimed composition with the prior art's composition which is commensurate in scope with the claimed invention.

See Final Office Action mailed October 8, 2008, at page 5.

To anticipate a claim, a reference must disclose, either explicitly or inherently, each element of the claim. *Verdegaal Bros. v. Union Oil Co. of Cal.*, 2 USPQ2d 1051, 1053 (Fed.

Cir. 1987). The prior art cited by the Examiner does not disclose each and every element of rejected claim 23, either explicitly or inherently.

a. The prior art of record does not disclose substances possessing the properties of the combination claimed in the rejected claims

To establish anticipation, a single prior art reference must disclose, either expressly or inherently, all elements of the claim at issue including the functional limitations. *In re Schreiber*, 128 F.3d 1473, 1478 (Fed. Cir. 1997); *In re Swinehart*, 439 F.2d 210, 212 (C.C.P.A. 1971). *See also In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007). Functional language in the claims cannot be ignored. *In re Graselli*, 231 U.S.P.Q. 393, 394 (BPAI 1983). The prior art of record plainly does not provide an explicit disclosure of a pharmaceutical combination that “possesses enhanced therapeutic properties in comparison with said active medicinal substance alone, said enhanced therapeutic properties being enhanced therapeutic effectiveness or reduced side effects.” Therefore, the only issue for Board’s consideration is whether any prior art of record inherently anticipates the rejected claims.

The undersigned is aware that a recitation of a newly discovered property may not make an old product patentable. *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985). The undersigned is also aware that a new use for an old product may not make a claim to the product patentable. *Schrieber*, 128 F.3d at 1477. However, neither of these factual and legal scenarios is present with respect to the rejection at issue. Quite simply, the claimed combination and the substances disclosed in the prior art are different and have different properties.

A finding of inherent anticipation requires a showing that, while not disclosed explicitly, the prior art composition possesses the properties of the claimed composition. MPEP §2112. *See also Schrieber*, 128 F.3d at 1478. The process established in the law for evaluating inherent anticipation includes two steps. *Id.* The Examiner must first come forward with a *prima facie* case of inherent anticipation. *Id.* If the Examiner satisfied the burden, the Applicant may rebut the *prima facie* case by making the requisite evidentiary showing. *Id.* To make a *prima facie* case of inherent anticipation, the Examiner must come forth with a scientific rationale or objective evidence tending to show inherency. *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). Only if the Examiner successfully sets forth the requisite evidence or rationale, then and only then the burden shifts to the patent applicant to come forward with an evidentiary showing

to rebut the *prima facie* case of inherent anticipation. *Rijckaert*, 9 F.3d at 1534. The Examiner did not present any evidence or provided any scientific rationale to set forth a *prima facie* case of inherency with respect to the missing functional language in the rejected claims on appeal. Instead, the Examiner merely asserted that “applicant has not presented data comparing the claimed composition with the prior art’s composition which is commensurate in scope with the claimed invention.” *See* Final Office Action mailed October 8, 2008, at page 5. It is submitted that neither quantity nor quality of Applicant’s showing is at issue until the Examiner meets the burden of coming forward with a *prima facie* case of inherency.

Furthermore, Applicants maintain that meeting the Examiner’s *prima facie* burden would be difficult under the circumstances. The functional language of the rejected claims recites certain properties of the claimed combination in comparison with the medicinal substance alone. It is not clear that any evidence or reasoning could show that a substance disclosed in the prior art would have enhanced therapeutic properties in comparison with itself. Plainly, if any combination or substance does not possess such properties, it is covered by the claims on appeal. Conversely, any prior art that does not possess such enhanced properties cannot anticipate the claims on appeal. The medicinal substances of the prior art, disclosed in standard therapeutic doses, do not and cannot possess the claimed properties. The rejected claim 23 covers only the pharmaceutical combinations having the unique claimed properties, and nothing more.

Accordingly, Applicants submit that the rejection of claims 23, 25-27, 29-34 and 38-45 as anticipated under 35 U.S.C. § 102(b) cannot be sustained even on this basis alone.

b. The prior art of record does not disclose a pharmaceutical combination containing a homeopathic dilution of a substance admixed with or incorporated with a therapeutic dose of the substance

To establish anticipation, the prior art must disclose all elements of the claim at issue arranged as in the claim. MPEP § 2131, *citing, In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). The prior art of record does not include an explicit disclosure of a pharmaceutically-active combination that comprises a therapeutic dose and a homeopathic dilution admixed with or incorporated with one another. Therefore, the only issue for Board’s consideration is whether the prior art of record inherently anticipates rejected claims.

According to the Examiner, “applicant has not pointed out how the structural formula of a therapeutic medicine differs from the structural formula of a homeopathic dilution of said

medicine.” *See* Final Office Action mailed October 8, 2008, at pages 4-5. In effect, the Examiner has asserted that the homeopathic dilution is not present in the claimed combination and has no effect on its properties. However, as shall be discussed below, the file wrapper includes indisputable evidence to the contrary. Examiner’s position ignores the essence of the applicants’ discovery, namely, that the homeopathic dose modifies the properties of the therapeutic dose of the same substance and that the claimed combination plainly differs from the substances disclosed in the prior art.

Furthermore, the law of inherent anticipation requires definiteness and certainty that the substance of the prior art inherently possess the properties of the claimed substance. Just because there is some possibility or probability that the prior art discloses the claimed invention does not render the claimed invention anticipated. *In re Oelrich*, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981) (stating that “[t]he mere fact that a certain thing may result from a given fact of circumstances is not sufficient” to establish inherency).

The case of *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) is illustrative. The claim at issue recited a diaper having a dedicated fastening means for disposal. The prior art diaper was in most respect identical, except it did not have a dedicated fastener for disposal, suggesting instead the use of another existing fastening means. The court emphasized that “that means is separate from and in addition to the other mechanical fastening means and performs a different function than they do [*emphasis added*].” *Id.* In reversing the holding of anticipation, the Court of Appeals for the Federal Circuit stated:

The Board ruled that one of the fastening means for attaching the diaper to the wearer also could operate as a third fastening means to close the diaper for disposal and that Wilson [prior art] therefore inherently contained all the elements of claim 76. In doing so, the Board failed to recognize that the third mechanical fastening means in claim 76, [], was separate from and independent of the other two mechanical means used to attach the diaper to the person [*emphasis added*].

*Id.*

The facts in the present appeal are similar to the facts of *Robertson*. In *Robertson*, the Examiner refused to acknowledge the separate and distinct nature and function of the claimed dedicated means for disposal. In the present appeal, the Examiner likewise chose to ignore the separate and distinct nature and function of the homeopathic dose in the claimed pharmaceutical



combination. In *Robertson*, the rejection was based on the perceived probability or possibility that the existing fastener of the prior art may play the role of the claimed dedicated fastening means for disposal. In the present appeal, the Examiner has suggested that “the claimed composition encompass nothing more than combining the same medicine in different concentration resulting in medicine disclosed in the prior art of record.” See Final Office Action mailed October 8, 2008, at pages 4-5. In other words, the Examiner suggested the possibility or probability that the homeopathic dilution does not add anything meaningful to the therapeutic dose of the substance in the claimed combination. Even in the absence of direct evidence to the contrary, an allegation of such possibility cannot be the basis for reading explicit limitations out of the claims. In *re Oelrich*, 212 U.S.P.Q. at 326 (holding that inherency “may not be established by probabilities or possibilities”).

Accordingly, Applicants submit that the rejection of claims 23, 25-27, 29-34 and 38-45 as anticipated under 35 U.S.C. § 102(b) cannot be sustained even on this basis alone.

c. The evidence demonstrating that the claimed combination possesses different properties cannot be ignored

However, the evidence in the file wrapper is directly contrary to the Examiner’s allegation that the substances of the prior art and the claimed combination are identical. The *Epstein Declaration*, which was filed with the paper of February 8, 2008, includes a comparison between several bipathic combinations and the corresponding standard therapeutic doses of the medicinal substance, including ethanol, morphine, cyclophosphane, prednizolon, and phenazepam. For example, the combined administration of a homeopathic dose of prednisolone with a standard dose (20 mg/rat) resulted in 1.8 times increase in migration ability of the peritoneal macrophages and 43.5% increase in biosynthetic ability of lymphocytes in comparison with the therapeutic dose alone (*Epstein Declaration*, par. 6). A 14-days and 4-months co-administration of a homeopathic dilution of ethanol with 5% ethanol solution resulted in 2-fold increase in concentration of ethanol in the blood in rat (*Epstein Declaration*, par. 14). Co-administration of a homeopathic dose of cyclophosphane with its therapeutic dose (125 mg/kg) led to a 2-fold decrease in the number of metastases and a 13% increase in inhibition index in mice in comparison with cyclophosphane alone (*Epstein Declaration*, par. 19). The homeopathic dose of phenazepam showed considerable enhancement in the therapeutic effectiveness of phenazepam’s anxiolytic effect (*Epstein Declaration*, par. 21). The *Epstein*

*Declaration* also presented the results of a human clinical study of the bipathic medication for the treatment of alcoholism-related conditions (*Epstein Declaration*, pars. 24-40). The *Epstein Declaration* clearly supports the viability of the bipathy phenomena across different groups of therapeutic substances, *in vitro*, *in vivo* and in a human clinical model.

The Examiner has stated that the scope of showing in the *Epstein Declaration* is not commensurate with the scope of the rejected claims. As had been discussed earlier, the Examiner did not meet the burden of coming forward with a *prima facie* case of inherency. Further, even if the Examiner's burden were met, rebuttal of *prima facie* case of inherency only requires an evidentiary showing that the prior art does not disclose substance or composition identical to the claim. *In re Graselli*, 713 F.2d 731, 739 (Fed. Cir. 1983).

The cited prior art discloses several well-known pharmaceutically-active substances at standard therapeutic doses. The Examiner selected references that disclose atropine sulfate, aspirin, insulin zinc, prednisolone, and sarcosyl, but any prior art that discloses any pharmaceutically active compound would provide the basis for the rejection of claim 23. The *Epstein Declaration* contains evidentiary showing for ethanol, morphine, cyclophosphane, prednisolon, and phenazepam. Claim 23 recites a broad range of bipathic medications. The evidence in the *Epstein Declaration* consistently establishes that a homeopathic dose of a substance effects properties of the therapeutic dose. Therefore, *Epstein Declaration* is evidence that a pharmaceutical combination containing a specific substance in a therapeutic treated with a homeopathic dose of the same substance and thus covered by claim 23 will not be identical to the therapeutic dose of the substance alone. It is submitted that evidence for each possible pharmaceutical active and/or for specific pharmaceutical actives disclosed in the prior art of record is not necessary.

Furthermore, the rejected claims at issue do not cover all bipathic medications, but only those bipathic combinations that possess the claimed properties, namely, "enhanced therapeutic effectiveness or reduced side effects" in comparison with the active medicinal substance alone. If a combination does not possess the claimed properties, it is not covered by claim 23 and the showing is not relevant to the patentability of such combination. In addition, the evidence of record does establish that the relevant prior art cannot include compositions with recited properties since the prior art does not disclose treatment with a homeopathic dilution. It is

therefore submitted that the scope of showing in the *Epstein Declaration* is fully commensurate with the scope of the claims.

On the basis of the foregoing, it is submitted that the rejection of claims 23, 25-27, 29-34 and 38-45 as anticipated under 35 U.S.C. § 102(b) cannot be sustained.

B. Rejection of Claims 17 and 19-21 as Anticipated under 35 U.S.C. § 102(b) by the Prior Art of Record

Claims 17 and 19-21 stand rejected as anticipated by *Jonsson*.

Independent claim 17 recites:

17. A method of making a bipathic medication, comprising the steps of:  
    providing an active medicinal substance in a therapeutic dose;  
    providing a homeopathic dilution of said active medicinal substance; and  
    admixing or incorporating said therapeutic dose and said homeopathic dilution with one another thus producing said bipathic medication.

The invention of the rejected claim 17 recites a method of making a pharmaceutical combination in which a therapeutic dose of a medicinal substance is admixed with (treated by) a homeopathic dilution of the same medicinal substance.

In the final Office Action, the Examiner did not articulate the reasoning related specifically to the alleged unpatentability of claim 17. It is submitted that the arguments provided in the section 8.A above are fully applicable with respect to claims 17 and 19-21. In addition, it is submitted that the rejected claim 17 includes a positive recitation of the steps “providing a homeopathic dilution of said active medicinal substance” and “admixing or incorporating said therapeutic dose and said homeopathic dilution with one another.” Even if the homeopathic dose of a substance were completely subsumed in the therapeutic dose as alleged by the Examiner, a finding of anticipation for a claim to a method of making would require that the prior art contain a disclosure of the specifically recited steps at issue. MPEP §2131, citing, *Verdegaal Bros. v. Union Oil Co. of Cal.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicants note that the prior art of record does not include any disclosure of homeopathic dilutions, let alone a disclosure of the steps of “providing a homeopathic dilution of said active medicinal

substance” and “admixing or incorporating said therapeutic dose and said homeopathic dilution with one another.”

On the basis of the foregoing, it is submitted that the rejection of claims 23, 25-27, 29-34 and 38-45 as anticipated under 35 U.S.C. § 102(b) cannot be sustained.

C. Rejection of Claims 23, 25-27, 29-34 and 38-45 as Obvious under 35 U.S.C. § 103 Over the Prior Art of Record

In the final Office Action, the Examiner did not articulate the reasoning related specifically to the obviousness rejection. Applicants expect the Examiner will do so in the Examiner’s Answer and thus reserve the right to address this ground of the rejection in further detail in the Reply Brief.

A finding of obviousness for a claimed combination of known elements requires a showing that “there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR Int’l v. Teleflex, Inc.* 127 S. Ct. 1727, 1741 (2007). To set forth a *prima facie* case of obviousness over a reference, the Examiner must show that the reference provides one skilled in the art with the reason to modify the teachings of the reference in the direction of claimed invention as a whole. MPEP §2141.02. The prior art of record simply does not provide any reason to modify a therapeutic dose of a well-known pharmaceutical substance in the direction of the claimed bipathic combination. The reason for making the modification for the inventors was the discovery described in the application at issue in the present appeal. The treatment of pharmaceutically active compounds with homeopathic dilution to enhance its therapeutic effectiveness was quite simply unknown prior to the filing of the patent application on appeal.

Furthermore, the claims recite a combination that possesses enhanced therapeutic properties in comparison with the active medicinal substance alone. It is an axiom that “a compound and its properties are inseparable.” *In re Papesh*, 137 USPQ 43, 51 (CCPA 1963). It is also well-established in the law that “obviousness cannot be predicated on what is not known at the time the invention is made, even if the inherency of a certain feature is later established.” *In re Rijckaert*, 28 USPQ2d 1955 (Fed. Cir. 1993). The prior art of record does not provide any information with respect to the missing functional language of the rejected claims.

On the basis of the foregoing, it is submitted that the rejection of claims 23, 25-27, 29-34 and 38-45 as obvious under 35 U.S.C. § 103 cannot be sustained.

D. Rejection of Claims 17 and 19-21 as Obvious under 35 U.S.C. § 103 Over the Prior Art of Record

The Examiner did not articulate the reasoning related to the alleged obviousness of claim 17 in the final Office Action.

It is submitted that the arguments provided in the section 8.C herein above are fully applicable with respect to claims 17 and 19-21. In addition, it is submitted that the rejected claim 17 includes a positive recitation of the steps “providing a homeopathic dilution of said active medicinal substance” and “admixing or incorporating said therapeutic dose and said homeopathic dilution with one another.” Even if the homeopathic dose of a substance were completely subsumed in the therapeutic dose of the substance, a finding of obviousness would require that the prior art of record provide some disclosure of the recited steps at issue and/or an articulated to reasoning to modify the prior art. *KSR Int’l v. Teleflex, Inc.* 127 S. Ct. 1727, 1741 (2007).

## CONCLUSION

Appellants submit that claims 17, 19-21, 23, 25-27, 29-34 and 38-45 meet the requirements for patentability under §§ 102 and 103. Accordingly, reversal of the Examiner's rejections is appropriate and is respectfully solicited.

Respectfully submitted,

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Dated: May 8, 2009

/Edward D. Pergament/  
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## CLAIMS APPENDIX

17. A method of making a bipathic medication, comprising the steps of:  
providing an active medicinal substance in a therapeutic dose;  
providing a homeopathic dilution of said active medicinal substance; and  
admixing or incorporating said therapeutic dose and said homeopathic dilution with one another thus producing said bipathic medication.

19. The method of claim 17, wherein said admixing or incorporating step comprises impregnating said therapeutic dose with said homeopathic dilution.

20. The method of claim 19, wherein said bipathic medication is in the form of a liquid.

21. The method of claim 17, wherein said bipathic medication is in the form of a paste.

23. A bipathic medication, comprising a pharmaceutically active combination of  
i) a therapeutic dose of an active medicinal substance; and  
ii) a homeopathic dilution of said active medicinal substance;  
said active medicinal substance and said homeopathic dilution being admixed or incorporated with one another;

wherein said pharmaceutically-active combination possesses enhanced therapeutic properties in comparison with said active medicinal substance alone, said enhanced therapeutic properties being enhanced therapeutic effectiveness or reduced side effects.

25. The medication of claim 23, wherein said therapeutic dose of said active medicinal substance is impregnated with said homeopathic dilution.

26. The medication of claim 23, wherein said homeopathic dilution and said therapeutic dose of said active medicinal substance-are admixed with one another in a liquid state.

27. The medication of claim 23, wherein said homeopathic dilution and said therapeutic dose of said active medicinal substance-are admixed with one another.

29. The medication of claim 23, wherein said active medicinal substance is atropine sulfate.

30. The medication of claim 23, wherein said active medicinal substance is acetylsalicylic acid.

31. The medication of claim 23, wherein said active medicinal substance is prednizolon.

32. The medication of claim 23, wherein said active medicinal substance is insulin.

33. The medication of claim 23, wherein said active medicinal substance is zinc.

34. The medication of claim 23, wherein said active medicinal substance is sarcosylsin.

38. The medication of claim 29, wherein said homeopathic dilution is a C30 potency dilution.

39. The medication of claim 30, wherein said homeopathic dilution is a C30 potency dilution.

40. The medication of claim 31, wherein said therapeutic dose is 1.00 ml of prednizolon.

41. The medication of claim 40, wherein said homeopathic dilution has C12 potency.

42. The medication of claim 32, wherein said homeopathic dilution is a C30 potency dilution.

43. The medication of claim 33, which is in the form of a paste.

44. The medication of claim 34, which is in the form of aqueous solution of potassium chloride.

45. The medication of claim 35, wherein said homeopathic dilution has a C200 potency.

46. A method of treating a disease or condition in a mammal, said method comprising administering to said mammal a bipathic medication of claim 23.

47. The method of claim 46, wherein said therapeutic dose and said homeopathic dilution are admixed or incorporated with one another prior to administration.

48. The method of claim 46, wherein said mammal is human.



## EVIDENCE APPENDIX

None.

## RELATED PROCEEDINGS APPENDIX

None.